K133182

APR 0 9 2014

Section 5 – 510(k) Summary

GC AMERICA INC.
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1. Submitter Information:

GC AMERICA INC.
3737 W. 127th Street
Alsip, IL 60803

Contact Person: Mark Heiss, D.D.S.
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Date Prepared: October 7, 2013

2. Device Name:

Proprietary Name: HTFX-222
Classification Name: Tooth shade resin material
Device Classification: Class II, 872.3690
Product Code: EBF

3. Predicate Devices:

Company	Device	510(k) No.	Date Cleared
GC America Inc.	MFP-051	K123631	07/23/2013
GC America Inc.	GC KALORE (GDLS-200)	K082434	11/14/2008
GC AMERICA, INC	G-aenial Universal Flo (GCUC-505)	K091388	07/22/2009
KERR CORPORATION	PREMISE	K032921	11/13/2003
Ivoclar Vivadent. Inc.	Tetric Evoceram	K042819	11/09/2004

4. Description of Device:

HTFX-222 is a light cured nano-filled radiopaque composite resin filled in a syringe. The device is a universal type. The material is available in 8 shades: A1, A2, A3, A3.5, A4, AO2, AO3 and CV .

5. Indications for Use:

1. Liner or base
2. Blocking out undercuts
3. Repair of direct and indirect aesthetic restorations: composites, veneers, crowns and bridges (including temporary crowns and bridges), defect margins when margins are in enamel
4. Sealing hypersensitive areas
5. Fissure sealant
6. Direct restorative for small Class I, II, III, IV, and V cavities

6. Technological characteristics:

All the components of the applicant device, HTFX-222, have already been used in the predicate devices. The curing mechanism of the predicates is polymerization of uncured methacrylate ester monomers. This reaction is caused by photo initiator system.

7. Substantial equivalence:
The applicant device complies with all the requirements of ISO 4049: 2009 (Dentistry - Polymer-based restorative materials).

The curing mechanism of the new and predicate devices is substantially equivalent in principle. Therefore, the new and predicate devices are the same in function, and similar in composition and intended use. This supports that the compatibility and safety of the applicant device are substantially equivalent to the predicate devices.

Differences
The following differences may be noted between the predicate devices and HTFX-222:
- All products listed under "Performance Test Results" (Table 18) meet ISO 4049 and differences in Depth of Cure, Flexural Strength and Water Sorption are noted.

8. Performance Bench Tests
It is confirmed that the device conforms to the required specifications of ISO 4049:2009 and is suitable for its intended use. Performance testing includes:
- Sensitivity to ambient light
- Depth of cure
- Flexural strength
- Water sorption
- Solubility
- Color stability after irradiation and water sorption
- Radiopacity

9. Shelf Life Evaluation and Storage Conditions:
- Shelf Life 3 years
- Store in a cool and dark place. 4-25°C (39.2 - 77.0°F)

	Applicant device	Comparative device				
Trade name	**HTFX-222**	**MFP-051**	**GC KALORE(GDLS-200)**	**PREMISE**	**Tetric Evoceram**	**G-aenial Universal Flo (GCUC-505)**
Product category	Light-cured radiopaque universal composite restorative	Light-cured radiopaque universal composite restorative	Light-cured radiopaque universal composite restorative	Universal nano-filled composite	Light-curing, universal nano-hybrid composite material for high-end standard restorations in the anterior and posterior regions	UNIVERSAL LIGHT-CURED RADIOPAQUE FLOWABLE COMPOSITE
Company	GC Corporation	GC Corporation	GC Corporation	KERR CORPORATION	Ivoclar Vivadent. Inc.	GC Corporation
510(k) No.	-	-	K082434	K032921	K042819	K091388
Indications for use	1. Liner or base 2. Blocking out undercuts 3. Repair of direct and indirect aesthetic restorations: composites, veneers, crowns and bridges (including temporary crowns and bridges), defect margins when margins are in enamel 4. Sealing hypersensitive areas 5. Fissure sealant 6. Direct restorative for small Class II, III, IV, I and V cavities	1. Direct restorative for class I, II, III, IV, V cavities. 2. Direct restorative for wedge-shaped defects and root surface cavities. 3. Direct restorative for veneers and diastema closure.	GDLS is a light-cured micro-filled radiopaque resin for the restoration of both anterior and posterior teeth. GDLS-200 consists of two delivery systems, Unitip(capsules for single dose) and Syringes. The GDLS-200 system is available in a variety of shades.	Premise is a dental composite restorative material intended to be used in all classes of cavities.	• Anterior restorations(Class III, IV) • Class V restorations (cervical caries, root erosion, wedge-shaped defects) • Restorations in the posterior region (Class I and II) • Veneering of discolored anterior teeth • Splinting of mobile teeth • Repair of composite and ceramic veneers	1. Restoration of class I, II, III, IV, V cavities. 2. Restoration of root surface caries 3. Restoration of deciduous teeth 4. Filling tunnel shaped cavities 5. Sealing hypersensitive areas 6. Liner/base/filling in cavity undercuts 7. Sealant 8. Splinting mobile teeth 9. Additions to composite restorations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

GC AMERICA INCORPORATED
Mark Heiss, D.D.S.
3737 W. 127th Street
Alsip, Illinois 60803

Re: K133182
Trade/Device Name: HTFX-222
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: II
Product Code: EBF
Dated: February 24, 2014
Received: March 4, 2014

Dear Dr. Heiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: HTFX-222

Indications for Use:

1. Liner or base
2. Blocking out undercuts
3. Repair of direct and indirect aesthetic restorations: composites, veneers, crowns and bridges (including temporary crowns and bridges), defect margins when margins are in enamel
4. Sealing hypersensitive areas
5. Fissure sealant
6. Direct restorative for small Class I, II, III, IV, and V cavities

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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